Good Laboratory Practices

CLIA Non-Waived Tests – Highly Complex

Required

- Obtain Federal CLIA (Clinical Laboratory Improvement Amendments – 1988) Certificate of Compliance or Certificate of Accreditation

  Application www.cms.hhs.gov/clia

- Perform any test categorized by FDA (Federal Drug Administration) as waived + moderate & high complexity tests listed on your CLIA certificate

  List www.accessdata.fda.gov/scripts/cdrh/cfdoc/cfCLIA/search.cfm

- Follow manufacturer's instructions and agency's requirements

  For compliance regulations www.cms.hhs.gov/clia
  CLIA Regulations & Federal Register Documents (left column)

  For accredited standards – follow agency requirements

Personnel qualifications www.cms.hhs.gov/clia CLIA Regulations & Federal Register Documents (left column)

- Director – 493.1443 (duties 493.1445)
- Clinical Consultant – 493.1455 (duties 493.1457)
- Technical Supervisor – 493.1449 (duties 493.1451)
- General Supervisor – 493.1461 & 493.1462 (duties 493.1463)
- Cytology General Supervisor – 493.1469 (duties 493.1471)
- Cytology Testing Personnel – 493.1483 (duties 493.1485
- Testing Personnel – 493.1489 & 493.1491 (duties 493.1495)

Oversight

- Cost – varies by agency and test volume every 2 years
- Surveys – every two years

  State agencies schedule visits within 2 weeks

  Accrediting agencies scheduled versus unannounced = varies